

# SEXUALLY TRANSMITTED DISEASES TESTING IN CALIFORNIA 2000 Annual Clinical Laboratory Survey Summary

## Introduction

Since 1996, the California Department of Health Services (DHS), Division of Communicable Disease Control, Sexually Transmitted Diseases (STD) Control Branch has surveyed clinical laboratories throughout California that perform testing for syphilis, gonorrhea, or chlamydia.

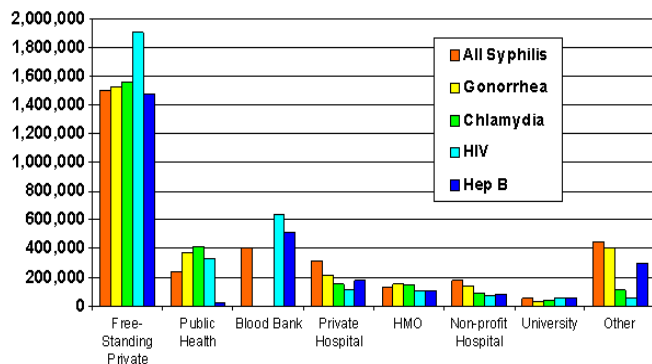
The Annual Clinical Laboratory Survey assists disease control efforts by identifying the number and types of laboratories performing STD testing, the number of tests performed, and trends in the use of test technologies.

Timely, accurate, and complete laboratory reporting of communicable diseases is essential to health department efforts to effectively identify public health problems and to design cost-effective interventions. Case reports also are used to intervene with individual patients and defuse potential outbreak situations. Although California regulations require both health care providers and laboratories to report selected STD to their local health departments, the majority of disease reports are initially received from laboratories.

Laboratories are legally mandated to report findings indicative of syphilis, gonorrhea, chlamydia, hepatitis B, and chancroid to local health departments for case follow-up activity and epidemiologic analysis. Acquired immune deficiency syndrome (AIDS) is a reportable condition. Non-names-based human immunodeficiency virus (HIV) reporting became mandatory in California on July 1, 2002.

This report summarizes information from the 2000 Annual Clinical Laboratory Survey. These data are presented along with disease trend information from the STD in California 2000 report.

**Figure 1. Number of STD Tests Performed, by Type of Laboratory, 2000**



Source: California DHS STD Control Branch

## Overview

The 2000 Annual Clinical Laboratory Survey was sent to 690 laboratories that potentially conducted testing for reportable diseases. Of the 547 eligible labs, 512 (94%) responded to the survey (see technical note for further explanation, page 4).

In 2000, private sector (non-public health) laboratories performed the majority of all reported STD tests (Figure 1). Private labs conducted 92.8% of syphilis, 86.9% of gonorrhea, 85.8% of chlamydia, and 91.2% of HIV tests. Free-standing private facilities performed the largest proportion (49.6%) of all syphilis, gonorrhea, chlamydia, and HIV tests combined (Figure 2).

**Figure 2. Combined Percent of Syphilis, Gonorrhea, Chlamydia, and HIV Tests Performed, by Laboratory Type**

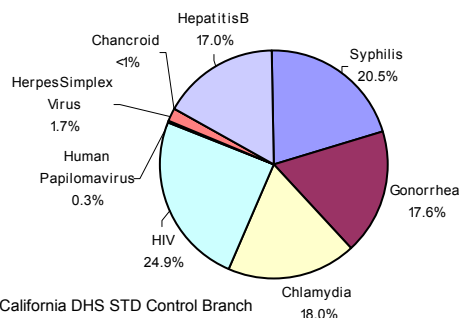
Laboratory Type	1997 N=12,009,381	1999 N=11,883,545	2000 N=13,070,927
Free-Standing Private	30.4%	40.2%	49.6%
Public Health	9.4%	10.6%	10.4%
Blood Bank	12.3%	10.3%	7.9%
Private Hospital	8.1%	8.1%	6.2%
Non-profit Hospital	9.0%	3.6%	3.6%
HMO*	10.5%	11.2%	4.1%
University/Teaching Hospital	n/a	1.3%	1.4%
VA**/Military Hospital	1.1%	1.3%	1.1%
Physicians/Group Practice	2.0%	1.1%	1.1%
Student Health Services	0.4%	0.5%	0.4%
Community Clinic Lab	0.4%	0.4%	0.4%
Correctional Facility	0.8%	0.3%	0.3%
Other	15.5%	11.0%	13.6%

\*Health Maintenance Organization \*\*Veterans Administration

Source: California DHS STD Control Branch

Of the 16,113,697 laboratory tests performed to detect STDs, the largest proportion was for HIV (24.9%), followed by syphilis (20.5%), chlamydia (18.0%), and gonorrhea (17.6%) (Figure 3).

**Figure 3. STD Tests Performed, 2000**

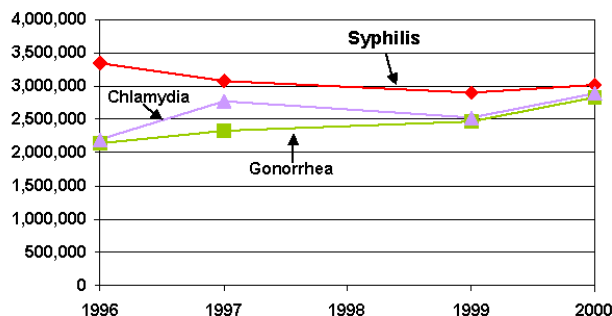


Source: California DHS STD Control Branch

## Testing for Bacterial STDs

For each of the reportable bacterial STDs, information from California's case-based surveillance system is included to provide a context for interpreting laboratory survey information. The overall total number of tests for chlamydia, gonorrhea, and syphilis is represented in Figure 4.

**Figure 4. Chlamydia, Gonorrhea, and Syphilis\*, Total Number of Tests**



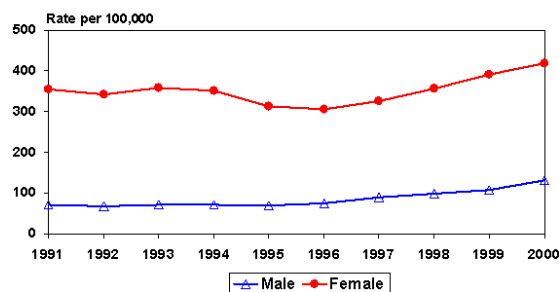
\*Non-Treponemal Syphilis Tests

Source: California DHS STD Control Branch

### Chlamydia

- *Chlamydia trachomatis* remains the most commonly reported infectious disease in California and the United States.
- In 2000, the rate of chlamydia was 418.5 cases per 100,000 among females, and 130.9 per 100,000 among males. Rates have increased in both males and females since 1999 (Figure 5).

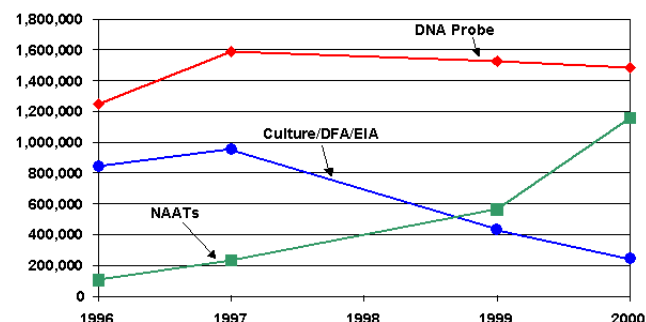
**Figure 5. Chlamydia, Rates by Gender, California, 1991–2000**



Source: California DHS STD Control Branch

- Based on lab survey data, a total of 2,893,116 chlamydia tests were performed in 2000, an increase of 14.4% (Figure 4) from 1999 (Appendix 1).
- Excluding serologies, which are not recommended for diagnosing acute infection, 3.6% of all reported lab tests for chlamydia were positive.
- Nucleic acid amplification testing (NAAT) in the form of ligase chain reaction (LCR), polymerase chain reaction (PCR), transcription mediated amplification (TMA), and strand displacement amplification (SDA) increased from 22.3% of tests in 1999 to 40.1% of tests in 2000 (Figure 6).

**Figure 6. Chlamydia Test Numbers, by Type of Test**



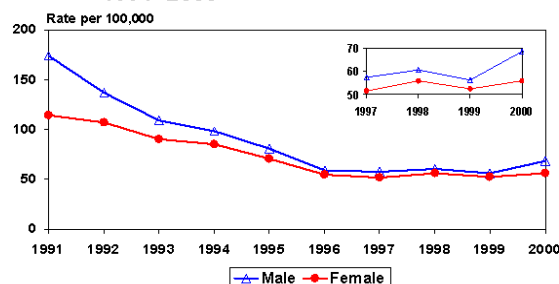
Source: California DHS STD Control Branch

- In 2000, the most commonly used chlamydia test was the DNA probe (51.3%), followed by NAAT (40.1%). Culture, direct fluorescent antibody (DFA), enzyme immunoassay (EIA), and other tests accounted for the remaining 8.6%.
- False positive STD test results cause unnecessary health care and emotional costs for patients and their partners. The Centers for Disease Control and Prevention (CDC) strongly recommends using verification assays to increase the specificity of DNA probes and EIA testing.<sup>3</sup> Less than half (41.4%) of laboratories reported performing verification assays in 2000.
- The National Chlamydia Laboratory Committee recommends performing negative gray zone supplemental testing to enhance the sensitivity of non-amplification test technologies. In 2000, 84.6% of labs that reported DNA probe testing repeated DNA probe findings in the gray zone.

### Gonorrhea

- *Neisseria gonorrhoeae* is the second most commonly reported infectious disease in California and the United States.
- Gonorrhea rates increased from 55.8 cases per 100,000 in 1999 to 63.5 per 100,000 in 2000. Rates have increased in both males and females (Figure 7).

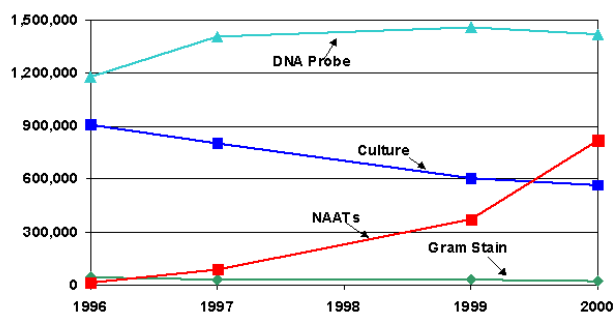
**Figure 7. Gonorrhea, Rates by Gender, California, 1991–2000**



Source: California DHS STD Control Branch

- The labs surveyed reported performing a total of 2,841,182 gonorrhea tests in 2000, an increase of 14.5% (Figure 4) from 1999 (Appendix 2).
- Overall, 0.7% of all reported lab tests for gonorrhea were positive.
- NAAT tests increased from 15.0% in 1999 to 28.9% in 2000 (Figure 8).

**Figure 8. Gonorrhea Test Numbers by Type of Test**



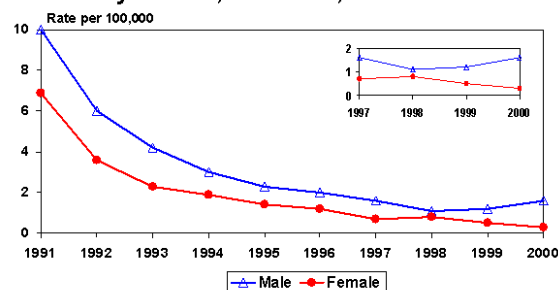
Source: California DHS STD Control Branch

- In 2000, the most commonly used gonorrhea test was the DNA probe (50.1%), followed by NAAT (28.9%), and culture (19.9%).
- Use of culture decreased 6.9% between 1999 and 2000. Because culture specimens are necessary to test for antibiotic susceptibility, the decreasing number of cultures collected may impact the ability to monitor antibiotic resistance. Current high levels of fluoroquinolone resistance have prompted new treatment guidelines in California.<sup>1</sup>
- Of laboratories that reported culture testing for gonorrhea, 47.1% reported beta-lactamase testing of isolates. Based on findings from the CDC Gonococcal Isolate Surveillance Project, which evaluates the antimicrobial resistance of *Neisseria gonorrhoeae*, penicillinase-producing *N. gonorrhoeae* is endemic at such levels that penicillin is no longer included as recommended treatment for gonorrhea. According to the CDC, monitoring beta-lactamase levels is of little clinical value and is unnecessary.

## Syphilis

- In 2000, the overall rate of primary and secondary syphilis was 1.0 cases per 100,000 in California. This represents a substantial decline from 1991, when the rate was 8.5 per 100,000.
- In 2000, the rate of syphilis was 0.3 per 100,000 among females, and 1.6 per 100,000 among males (Figure 9). Higher rates among males have been associated with outbreaks among men who have sex with men (MSM). The epidemic of syphilis among MSM has continued through 2001 and 2002 in California.

**Figure 9. Primary and Secondary Syphilis, Rates by Gender, California, 1991–2000**



Source: California DHS STD Control Branch

- Labs surveyed in California reported 3,297,031 tests for syphilis in 2000 (Appendix 3).
- Of all tests for syphilis, 91.6% were non-treponemal serology tests; 8.4% were treponemal serology tests. Few (424) were darkfield or direct fluorescent antibody *Treponema pallidum* (DFA-TP) tests.
- Of the reported non-treponemal serology tests, 1.9% were positive; 10.8% of all treponemal serology tests were positive.
- Rapid plasma reagin (RPR) accounted for 95.6% of all non-treponemal serology tests performed. Venereal Disease Research Laboratory (VDRL) tests accounted for 4.4%.
- Of labs that performed non-treponemal serology tests, 238 (54.3%) reported diluting “rough” tests to rule out prozone reactions. This practice is recommended by the CDC to increase the sensitivity of these tests in early syphilis and reduce false negative test results.
- Microhemagglutination assay *Treponema pallidum* (MHA-TP) accounted for 67.7% of treponemal serology tests. The MHA-TP has since been replaced by the *Treponema pallidum* particle agglutination (TP-PA) assay. Fluorescent treponemal antibody absorption (FTA-Abs) accounted for 15.1% of treponemal serology tests. EIA and other tests made up the remaining 17.2% of treponemal serology tests.

## Chancroid

- Only two cases of chancroid were reported in California in 2000.
- Twenty-five laboratories (5%) reported 5,182 tests for chancroid in 2000, all of which were cultures. Eleven of the tests were positive.

# Testing for Viral STDs

## Human Immunodeficiency Virus (HIV)

- Of the labs surveyed, 280 (54%) performed a total of 4,015,803 HIV tests.
- The majority (76.6%) of the tests performed were EIA screening tests. Confirmatory testing (Western blot and immunofluorescent assay (IFA)) accounted for 1.0% of all tests. Other tests included viral load tests (6.9%), qualitative PCR (6.8%), and Other (8.7%).
- Of the 3,078,698 EIA screening tests performed, 0.8% were positive.
- Of the 34,527 Western blots performed, 60.4% were positive; 89.3% of 2,232 IFA tests were positive.

## Hepatitis B

- Of the surveyed labs, 246 (48%) performed a total of 2,736,101 hepatitis B surface antigen tests.
- In 2000, 1.5% of reported hepatitis B surface antigen tests were positive.

## Human Papillomavirus (HPV)

- Eight laboratories (2%) included in the survey offered HPV DNA testing in 2000, performing a total of 43,739 tests. All tests were hybrid capture assays.
- Of HPV tests, 7,867 (18.0%) were positive.
- Because the sampling for this survey emphasized testing for bacterial STDs or HIV (e.g., cytopathology laboratories were not sampled), these totals may be an underestimate of testing activities.

## Herpes Simplex Virus (HSV)

- Of the labs included in the survey, 254 (50%) performed 281,544 HSV tests. Of these, 154,728 (55.0%) were culture, EIA or IFA; 126,816 (45.0%) were serologic tests.
- Of all non-serologic tests performed, 91.3% were culture tests, 25.9% of which were positive.
- Of serology tests reported, 92.7% were type-specific HSV-2 tests, 35.3% of which were positive. The remaining 7.3% of serologic tests were combined HSV-1 and HSV-2, with 55.4% positive tests. Serology tests that do not distinguish between HSV-1 and HSV-2 have limited clinical value.

# Summary

Survey data for 2000 documented more than 16 million STD tests in California.

The 2000 survey demonstrated an increase of 14.4% in the overall number of chlamydia tests performed since 1999. This increase likely reflects greater compliance with clinical guidelines for annual chlamydia screening among sexually active women 25 years of age and younger.

The use of amplified tests for chlamydia has increased, accounting for 40.1% of all chlamydia tests in 2000. NAAT technologies provide the greatest sensitivity, offer the advantage of using non-invasive specimen collection, and were recommended by the California Chlamydia Action Coalition (CCAC) beginning in 2001 (<http://www.ucsf.edu/castd/>).

Gonorrhea culture testing has decreased, accounting for 19.9% of all gonorrhea tests in 2000. This decline may adversely affect future antibiotic resistance testing. Current high levels of fluoroquinolone resistance have prompted new treatment guidelines in California.

## Additional Resources

<sup>1</sup>Information on disease trends, previous laboratory reports, surveillance reports, and treatment guidelines can be found at the STD Control Branch website: <http://www.dhs.ca.gov/ps/dcdc/STD/stdindex.htm>.

<sup>2</sup>Information about infectious disease reporting, including a list of reportable diseases and reporting laws, can be found at the Disease Investigations and Surveillance Branch website: <http://www.dhs.ca.gov/ps/dcdc/dsb/dsbindex.htm>.

<sup>3</sup>Recent CDC guidelines for chlamydia and gonorrhea testing: MMWR Oct 18 2002; 51(RR-15): 1-27. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5115a1.htm>

## Technical notes:

In June 2001, surveys were mailed to all laboratories that had indicated on the 1999 survey that they performed STD testing. Surveys were also mailed to laboratories that had been licensed after 1998.

Los Angeles County Department of Health Services' STD Control Program conducts a laboratory survey for laboratories located in Los Angeles County. All other laboratories in California are surveyed by the California DHS, STD Control Branch. Data from both surveys are merged for analysis.

Of 690 labs that received surveys, 143 indicated that they were draw stations only, had closed, or did not perform STD testing. Of the remaining 547 laboratories, 35 did not return the survey at all or did not provide sufficient information to include in the analysis. There were 512 laboratories that returned surveys with complete information.

The annual survey was not conducted in 1998.

Appendix 1: CHLAMYDIA TESTING IN CALIFORNIA, 1996-2000													
STD & Type of Test		Test Characteristics		Testing Year (# of responding laboratories)									
				1996		1997		1999		2000		TOTAL	
		PUBLIC (46)	PRIVATE (705)	TOTAL (751)	PUBLIC (44)	PRIVATE (637)	TOTAL (681)	PUBLIC (41)	PRIVATE (530)	TOTAL (571)	PUBLIC (40)	PRIVATE (472)	(512)
CHLAMYDIA Culture	# of tests	6,771	90,023	96,794	4,747	309,061	313,808	2,749	52,685	55,434	2,232	41,515	43,747
	# positive tests	478	2,428	2,906	318	2,096	2,414	82	1,105	1,187	69	1,861	1,930
	% positive*	7.1%	2.7%	3.0%	6.7%	0.7%	0.8%	3.0%	2.1%	2.1%	3.1%	2.1%	2.1%
CHLAMYDIA DFA	# of tests	8,305	69,548	77,853	5,145	116,481	121,626	3,259	46,844	50,103	3,473	33,088	36,561
	# positive tests	1,157	2,325	3,482	428	2,509	2,937	233	1,238	1,471	337	722	1,059
	% positive*	13.9%	3.3%	4.5%	8.3%	2.2%	2.4%	7.1%	2.6%	2.9%	9.7%	2.2%	2.9%
CHLAMYDIA EIA	# of tests	112,985	553,685	666,670	78,478	437,493	515,971	13,701	314,566	328,267	8,436	152,570	161,006
	# positive tests	6,020	18,726	24,746	3,879	16,794	20,673	1,193	10,529	11,722	555	7,501	8,056
	% positive*	5.3%	3.4%	3.7%	4.9%	3.8%	4.0%	8.7%	3.3%	3.6%	6.6%	4.9%	5.0%
CHLAMYDIA DNA Probe	# of tests	80,438	1,167,789	1,248,227	77,669	1,509,960	1,587,629	51,362	1,473,663	1,525,025	23,344	1,461,647	1,484,991
	# positive tests	1,827	34,396	36,222	2,671	31,521	34,192	2,003	48,279	50,282	1,148	41,397	42,545
	% positive*	2.3%	2.9%	2.9%	3.4%	2.1%	2.2%	3.9%	3.3%	3.3%	4.9%	2.8%	2.9%
CHLAMYDIA LCR	# of tests	18,608	12,896	31,504	82,460	46,878	129,338	212,341	212,964	425,305	173,180	210,865	384,045
	# positive tests	931	466	1,397	5,285	5,636	10,921	12,020	9,223	21,243	8,192	10,071	18,263
	% positive*	5.0%	3.6%	4.4%	6.4%	12.0%	8.4%	5.7%	4.3%	5.0%	4.7%	4.8%	4.8%
CHLAMYDIA PCR	# of tests	68,041	8,068	76,109	91,493	10,657	102,150	96,179	31,812	127,991	111,977	214,099	326,076
	# positive tests	5,305	305	5,610	6,087	121	6,208	6,543	925	7,468	8,001	6,649	14,650
	% positive*	7.8%	3.8%	7.4%	6.7%	1.1%	6.1%	6.8%	2.9%	5.8%	7.1%	3.1%	4.5%
CHLAMYDIA TMA	# of tests				2,202	-	2,202	11,217	-	11,217	9,953	104,565	114,518
	# positive tests				118	0.0%	118	519		519	321	5,874	6,195
	% positive*				5.4%		5.4%	4.6%	0.0%	4.6%	3.2%	5.6%	5.4%
CHLAMYDIA SDA	# of tests										81,508	252,771	334,279
	# positive tests										2,824	9,356	12,180
	% positive*										3.5%	3.7%	3.6%
CHLAMYDIA OTHER	# of tests	-	-	-	-	-	-	1,132	3,574	4,706	957	6,936	7,893
	# positive tests							59	260	319	47	262	309
	% positive*							5.2%	7.3%	6.8%	4.9%	3.8%	3.9%
CHLAMYDIA TOTAL	# of tests	295,148	1,905,793	2,200,941	342,194	2,435,016	2,777,210	391,940	2,136,108	2,528,048	415,060	2,478,056	2,893,116
	# positive tests	15,718	58,753	74,471	18,786	58,677	77,463	22,652	74,873	93,692	21,494	82,693	104,187
	% positive*	5.3%	3.1%	3.4%	5.5%	2.4%	2.8%	5.8%	3.5%	3.7%	5.2%	3.3%	3.6%

\*Percent positive was calculated using only those surveys that provided both the number processed and the number positive

## Appendix 2: GONORRHEA TESTING IN CALIFORNIA, 1996-2000

STD & Type of Test	Test Characteristics	Testing Year (# of responding laboratories)											
		1996				1997				1999			
		PUBLIC (46)	PRIVATE (705)	TOTAL (751)	PUBLIC (44)	PRIVATE (637)	TOTAL (681)	PUBLIC (41)	PRIVATE (530)	TOTAL (571)	PUBLIC (40)	PRIVATE (472)	TOTAL (512)
GONORRHEA Gram Stains	# of tests	9,817	34,040	43,857	7,656	23,461	31,117	3,380	26,828	30,208	5,397	16,189	21,586
	# positive tests	1,372	1,528	2,900	1,238	586	1,824	692	464	1,156	1,384	309	1,693
	% positive*	14.0%	4.5%	6.6%	16.2%	2.5%	5.9%	20.5%	1.7%	3.8%	25.6%	1.9%	7.8%
GONORRHEA Culture	# of tests	185,507	720,840	906,347	158,354	645,056	803,410	52,485	554,260	606,745	44,273	520,601	564,874
	# positive tests	5,993	6,104	12,097	4,603	5,721	10,324	1,674	3,874	5,548	69	861	930
	% positive*	3.2%	0.8%	1.3%	2.9%	0.9%	1.3%	3.2%	0.7%	0.9%	0.2%	0.2%	0.2%
GONORRHEA DNA Probe	# of tests	73,626	1,104,238	1,177,864	75,523	1,334,210	1,409,733	60,183	1,402,405	1,462,588	37,092	1,385,242	1,422,334
	# positive tests	540	9,115	9,655	812	7,103	7,915	710	11,702	12,412	635	12,704	13,339
	% positive*	0.7%	0.8%	0.8%	1.1%	0.5%	0.6%	1.2%	0.8%	0.8%	1.7%	0.9%	0.9%
GONORRHEA PCR	# of tests										8,100	16,704	24,804
	# positive tests										152	232	384
	% positive*										1.9%	1.4%	1.5%
GONORRHEA LCR	# of tests	4,735	7,959	12,694	52,685	33,966	86,651	196,665	175,050	371,715	289,076	195,992	485,068
	# positive tests	80	304	384	870	228	1,098	4,023	1,480	5,503	1,155	1,341	2,496
	% positive*	1.7%	3.8%	3.0%	1.7%	0.7%	1.3%	2.0%	0.8%	1.5%	0.4%	0.7%	0.5%
GONORRHEA TMA	# of tests										3,070	0	3,070
	# positive tests										0	0	0
	% positive*										0.0%	0.0%	0.0%
GONORRHEA SDA	# of tests										76,458	231,348	307,806
	# positive tests										863	1,260	2,123
	% positive*										1.1%	0.5%	0.7%
GONORRHEA OTHER	# of tests	-	-	-	-	-	-	1,732	8,192	9,924	948	10,692	11,640
	# positive tests	-	-	-	-	-	-	12	85	97	8	122	130
	% positive*	-	-	-	-	-	-	0.7%	1.0%	1.0%	0.8%	1.1%	1.1%
GONORRHEA TOTAL	# of tests	273,699	1,870,545	2,144,244	294,411	2,037,932	2,332,343	314,445	2,166,735	2,481,180	464,414	2,376,768	2,841,182
	# positive tests	7,998	17,075	25,073	7,667	13,640	21,307	7,111	17,605	24,716	4,114	16,597	20,711
	% positive*	2.9%	0.9%	1.2%	2.6%	0.7%	0.9%	2.3%	0.8%	1.0%	0.9%	0.7%	0.7%

\*Percent positive was calculated using only those surveys that provided both the number processed and the number positive

Appendix 3: SYPHILIS TESTING IN CALIFORNIA, 1999-2000									
STD & Type of Test		Test Characteristics	Testing Year (# of responding laboratories)						
			1999			2000			
			PUBLIC (41)	PRIVATE (530)	TOTAL (571)	PUBLIC (40)	PRIVATE (472)	TOTAL (512)	
Non-treponemal Serology									
SYPHILIS		# of tests	198,546	2,700,498	2,899,044	224,899	2,796,342	3,021,241	
RPR &		# positive tests	9,225	45,992	55,217	12,567	43,430	55,997	
VDRL		% positive*	4.6%	1.7%	1.9%	5.6%	1.6%	1.9%	
Treponemal Serology									
SYPHILIS		# of tests	3,051	42,667	45,718	2,040	39,494	41,534	
FTA-ABS		# positive tests	1,022	11,542	12,564	774	9,848	10,622	
		% positive*	33.5%	27.1%	27.5%	37.9%	24.9%	25.6%	
SYPHILIS		# of tests	11,240	188,215	199,455	11,560	174,965	186,525	
MHA-TP/TP-PA		# positive tests	5,061	13,405	18,466	5,456	13,052	18,508	
		% positive*	45.0%	7.1%	9.3%	47.2%	7.5%	9.9%	
SYPHILIS		# of tests	-	461	461	-	436	436	
EIA/Immunoglobulin G (IgG)		# positive tests	-	66	66	-	69	69	
		% positive*	0.0%	14.3%	14.3%		15.8%	15.8%	
SYPHILIS		# of tests	-	200,877	200,877	-	46,871	46,871	
Other Treponemal Serology		# positive tests	-	1,384	1,384	-	582	582	
		% positive*	0.0%	0.7%	0.7%	0.0%	1.2%	1.2%	
SYPHILIS		# of tests	14,291	432,220	446,511	13,600	261,766	275,366	
Total Treponemal		# positive tests	6,083	26,397	32,480	6,242	23,551	29,793	
		% positive*	42.6%	6.1%	7.3%	45.9%	9.0%	10.8%	
SYPHILIS		# of tests	545	58	603	391	33	424	
Darkfield/DFA-TP		# positive tests	29	2	31	12	-	12	
		% positive*	5.3%	3.4%	5.1%	3.1%	0.0%	2.8%	
Total Syphilis		# of tests	213,382	3,132,776	3,346,158	238,890	3,058,141	3,297,031	
		# positive tests	15,337	72,391	87,728	18,821	66,981	85,802	
		% positive*	7.2%	2.3%	2.6%	7.9%	2.2%	2.6%	

\*Percent positive was calculated using only those surveys that provided both the number processed and the number positive